

Appl. No. 10/025,668
AmdtAF. dated July 20, 2005
Reply to Final Office Action of May 20, 2005

REMARKS

Applicants have carefully reviewed the Final Office Action dated May 20, 2005, prior to preparing this response. Currently claims 1-35 are pending in the application, wherein claims 1-35 have been rejected by the Examiner. Favorable consideration of the following remarks is respectfully requested.

Claims 1-4 and 20-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dubrul (U.S. Patent No. 5,944,701). Applicants respectfully traverse this rejection. Dubrul fails to teach every limitation of the claimed invention, thus does not anticipate the rejected claims.

Contrary to the Examiner's assertion, Dubrul fails to teach a shape memory polymer jacket attached to and surrounding a portion of a core wire as currently claimed. A shape memory polymer is a distinct subset of polymers having unique thermo-mechanical properties not found in other polymers. These unique properties provide shaping and/or forming capabilities through selective heating and cooling of the shape memory polymer not offered by other polymers.

In giving claims their broadest reasonable interpretation, the Examiner is obligated to take into account "whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." M.P.E.P. §2111, quoting *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). In this case, the specification clearly defines a shape memory polymer. See Specification, page 4, line 17 through page 6, line 10. Additionally, the Examiner is constrained to interpret claim language consistent with the interpretation that those skilled in the art would reach. See M.P.E.P. §2111, citing *In re Cortright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art." M.P.E.P. §2111.01 II, citing *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 67 USPQ2d 1438 (Fed. Cir. 2003); *Brookhill-Wilk I, LLC v Intuitive Surgical, Inc.*, 334 F.3d 1294, 67 USPQ2d 1438 (Fed. Cir. 2003). One of ordinary skill in the art would understand that the term "shape memory polymer", as recited in the claims, is common terminology used to indicate a group of polymers having unique "memory" characteristics which react to heating at or above the glass transition temperature (Tg) of the polymer. This is indeed the ordinary and customary meaning given to the term "shape memory polymer" by those of

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ordinary skill in the art. It is apparent that the Examiner has unreasonably misconstrued the term "shape memory polymer", as recited in the claims, in formulating his rejection. The unreasonable interpretation relied on by the Examiner is contrary to the ordinary and customary meaning of the term accepted by those of ordinary skill in the art.

"Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." M.P.E.P. §2111.01 III, citing *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 53 USPQ2d 1065 (Fed. Cir. 1999). As defined in the specification, shape memory polymers are characterized by their ability to be selectively deformed from their permanent "memorized" shape at a temperature at or above their glass transition temperature (Tg) and then cooled below Tg to retain a temporary "programmed" shape different from the permanent shape. The shape memory polymer "remembers" the permanent shape, such that when the shape memory polymer is again heated at or above the glass transition temperature of the polymer, the polymer returns to its permanent shape if left unconstrained. The shape memory polymer may be repeatedly reshaped into various temporary shapes without compromising shapeability or guidewire performance, and the guidewire, if left unconstrained, will always return to its permanent shape upon heating at or above the glass transition temperature of the polymer.

In pointing out the characteristics of the polymer coating taught in Dubrul, the Examiner asserts that "[t]he shape memory properties of the polymer as disclosed in Dubrul are unmistakable." See Final Office Action, page 6. Applicants respectfully disagree with this statement. The polymer coating taught in Dubrul shows none of the unique thermo-mechanical "memory" properties characteristic of a shape memory polymer. As described by the Examiner, the polymer coating assumes a coiled configuration and must be forced into another configuration (i.e. straight). See Final Office Action, page 6 (emphasis added). It is the shape memory alloy core wire that forces the guidewire into a straight configuration as the shape memory alloy transitions from its martensitic phase to its superelastic austenitic phase. The polymer coating has a constant biasing coil force and always seeks to be in the coiled configuration. The biasing coil force of the polymer is greater than the force applied by the core wire in the martensitic phase, thus the polymer coating constrains the guidewire in a coil while the core wire is in the martensitic phase. See Dubrul, column 3, lines 37-39. The guidewire is

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straightened as the shape memory alloy core undergoes a transformation to a superelastic austenitic phase. See Dubrul, column 3, lines 40-44. In the superelastic configuration, the memorized shape of the shape memory alloy core wire exerts an opposing biasing force greater than the force of the polymer jacket, thus the core wire in the austenitic phase overcomes the coil biasing force of the polymer coating. The guidewire only returns to the coiled configuration when the shape memory alloy returns to the martensitic phase and the force exerted by the shape memory alloy core wire is again less than the constant biasing force of the polymer coating. Thus, the force exerted by the shape memory alloy core wire dictates transformation and recovery of the guidewire between a coiled configuration and a straightened configuration. The fact that the polymer jacket must be forced into another configuration indicates that the polymer jacket does not possess shape memory properties which the Examiner says are "unmistakably" present.

Contrary to the Examiner's assertion, shape memory properties of the polymer coating disclosed in Dubrul are not "unmistakable," and in fact are not present. A polymer coating constraining a guidewire in a coiled position, then forced from a coiled position to a straightened position due to a phase transformation of a shape memory alloy core wire, and again returning to its coiled position when the shape memory alloy core wire reverts back to its initial phase, is not indicative of a shape memory polymer. What Dubrul does indicate is the polymer coating has a biasing force that can overcome the configuration of the core wire in the initial phase of the shape memory alloy, but must succumb to the configuration of the core wire in the transformation phase of the shape memory alloy. This is clearly not indicative of a shape memory polymer, as erroneously asserted by the Examiner. **Transformation of a shape memory polymer is achieved by thermal stimuli, not physical stimuli by an external force as is the case in Dubrul.**

To the contrary, a shape memory polymer undergoes a transformation when the polymer is heated at or above its glass transition temperature. Thus, a shape memory polymer may have a memorized shape, be programmed to have a temporary shape, and may return to its original memorized shape upon heating the polymer at or above the glass transition temperature. Transformation of the shape memory polymer between the temporary shape and the original memorized shape is not dictated by any physical force exerted by the core wire. As stated in

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claim 1, the shape memory polymer jacket is more stiff than the portion of the core wire which it surrounds, thus the configuration of the shape memory polymer jacket is not controlled by the core wire (which is the case in Dubrul). Indeed, transformation of a shape memory polymer is controlled by heating the polymer at or above the glass transition temperature of the shape memory polymer.

Applicants assert the above discussion clearly distinguishes the currently claimed invention over Dubrul. The polymer coating taught in Dubrul does not have the unique thermo-mechanical properties associated with a shape memory polymer which allow the shape memory polymer to transform from a temporary shape to an original memorized shape. Therefore, Dubrul fails to disclose a metallic guidewire having a shape memory polymer jacket as claimed. Applicants assert claims 1-4 and 20-23 are clearly patentable over Dubrul and withdrawal of the rejection is respectfully requested.

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Gunatillake et al. (WO 01/07499). Applicants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established. Claim 17 recites a method of shaping a guidewire, wherein the guidewire comprises an elongate core wire with a shape memory polymer jacket attached to and surrounding a portion of the core wire. As discussed above, Dubrul fails to teach a guidewire with the structural limitations of the guidewire of claim 17. Applicants respectfully assert Gunatillake fails to remedy the shortcomings of Dubrul. Therefore, at least because not every element of the claimed invention is either taught or suggested by the prior art references, Applicants assert a *prima facie* case has not been established. See M.P.E.P. §2143.03. Therefore, claim 17 is believed to be in condition for allowance and withdrawal of the rejection is requested.

Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Lafontaine (U.S. Patent No. 5,662,621). Applicants respectfully traverse this rejection, asserting no *prima facie* case has been established. For the reasons stated above, as well as those provided in Applicants' previous responses, regarding the deficiencies of Dubrul and the fact that Lafontaine fails to remedy the shortcomings of Dubrul, Applicants assert each and every element of the claimed invention is not disclosed by the combination of references required to establish a *prima facie* case of obviousness.

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Additionally, there is no motivation to modify the device of Lafontaine. Applicants assert that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As disclosed in Lafontaine, the core provides stimulus (thermal, chemical or light) to the guide catheter for transitioning the guide catheter between a soft, straight state and a pre-shaped, relatively stiff, memory retention state. See column 5, lines 60-62. Once the guide catheter is positioned in the body, the core may be removed to allow completion of the catheterization procedure. See column 7, lines 23-28. Applicants assert treating the catheter shaft 22 as a polymer jacket and attaching the catheter shaft 22 to and surrounding the core 24 would render the Lafontaine invention nonfunctional and unsatisfactory for its intended purpose. If the catheter shaft were attached to the core, then the core would not be removable from the catheter shaft and a subsequent catheterization procedure could not be completed, thus making the device unsatisfactory for its intended purpose. Therefore, there is no motivation to modify Lafontaine as the Examiner suggests in combining the references.

Applicants assert, at least because each and every element of the claimed invention is not taught by the combination and there is no motivation to combine the references, a *prima facie* case of obviousness has not been established with the combination of references. Applicants assert claim 17, and therefore claims 18 and 19, are currently in condition for allowance and withdrawal of the rejection is requested.

Claims 5-16 and 24-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dubrul (U.S. Patent No. 5,944,701) in view of Takahashi (U.S. Patent No. 6,485,458). Claims 5-16 depend from claim 1 and claims 24-35 depend from claim 20. Therefore, for the reasons stated above concerning the allowability of claims 1 and 20, Applicants respectfully assert this rejection is moot.

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Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,



David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

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